

NOV 13 2003

To: United States Patent and Trademark Office

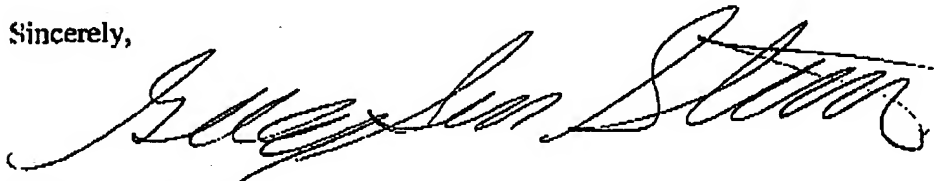
Fax: 703 308 4242

OFFICIAL

# REQUEST FOR STATUS CHECK

Please check the status of patent application #10/084,391. Attached is the last communication with your office including a copy of the express mail receipt. Please contact me by phone at 949 306 9491 or email at [ggsteiner@yahoo.com](mailto:ggsteiner@yahoo.com).

Sincerely,



Gregory Gene Steiner  
1676 Ala Moana Blvd. #104  
Honolulu, Hawaii 96815

DATE 07/19/2003  
APPLICATION NUMBER 10/084,391  
RESPONSE TO OFFICE ACTION DATED 06/05/2003  
FIRST NAMED APPLICANT Gregory Gene Steiner  
EXAMINER Jerome D Goldberg  
ART UNIT 1614

**ENCLOSED**

1. Notice of Non-Compliant Amendment
2. Copy of previously filed amendment
3. Clean version of the replacement section [0016]
4. Clean version of the replacement Claim 1

The Notice of Non-Compliant Amendment was mailed to my previous address. The USPTO has been noticed that my address has changed. Please send all future mailings to

Gregory Gene Steiner  
1676 Ala Moana Blvd. #104  
Honolulu, HI 96815



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,391	02/26/2002	Gregory Gene Steiner		8379

7590 06/05/2003  
Gregory Gene Steiner  
P O Box 61515  
Honolulu, HI 96839

EXAMINER

GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

### Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 3-4-03 is considered non-compliant because it has not been submitted in the format required under 37 CFR 1.121, as amended on September 8, 2000 (see 65 Fed. Reg. 54603, Sept. 8, 2000, and 1238 O.G. 77, Sept. 19, 2000).

- ☒ 1. The amendment does not include a clean version of the replacement paragraph(s)/section(s). 37 CFR 1.121(b)(1)(ii).
- ☐ 2. The amendment does not include a marked-up version of the replacement paragraph(s)/section(s). 37 CFR 1.121(b)(1)(iii).
- ☐ 3. The amendment does not include a clean version of the amended claim(s). 37 CFR 1.121(c)(1)(i).
- ☐ 4. The amendment does not include a marked-up version of the amended claim(s). 37 CFR 1.121(c)(1)(ii).
- ☐ 5. Other \_\_\_\_\_
- ☐ **PRELIMINARY AMENDMENT:** Unless applicant re-submits the preliminary amendment in compliance with revised 37 CFR 1.121 within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
- ☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").

*M. Pingle*  
Legal Instruments Examiner

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**NOV 13 2003**

**OFFICIAL**

**DATE 3-01-2003**

**APPLICATION NUMBER**

**10/084,391**

**RESPONSE TO OFFICE ACTION DATED**

**01-28-2003**

**FIRST NAMED APPLICANT**

**Gregory Gene Steiner**

**EXAMINER**

**Jerome D Goldberg**

**ART UNIT**

**1614**

**ENCLOSED**

**1. OFFICE ACTION SUMMARY**

**2. AMENDMENT B**

**Office Action Summary**

Applicati n No.

10/084,391

Applicant(s)

STEINER, GREGORY GENE

Examiner

Jerome D Goldberg

Art Unit

1814

~ The MAILING DATE of this communication appears on the cover sheet with the correspondence address ~

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

U.S. Patent and Trademark Office

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3-18-03

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The U.S. patents are cited to complete the record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Volz et al. reference.

The Volz et al. Reference having an effective date of January 1, 1997 teaches applicant's Kavain as having therapeutic use in patients (see TX, line 8) and shows oral administration at 270-330mg/day for 22/weeks (TX lines 8-20).

The instant claims are directed to preventing a condition which would read on a normal host. Therefore, one skilled in this art would find ample motivation from the prior art supra to employ a known pharmaceutical kavain for preventing a condition with a reasonable expectation that said compound would be effective. Moreover, in the 24 weeks of treatment their would be a time wherein the patient was cared and still received the pharmaceutical.

Changing the mammal to a "mammal in need thereof" would overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by the Hapka et al. reference.

The Hapka et al reference teaches toxicological studies of kavain in mammals (see ST line 3 and RN, line 1) clearly, toxicity studies would be administering to a normal mammal. Changing the mammal to a "mammal in need thereof" would overcome this rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-6 of copending Application No. 09/ 792,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed applicant's compound for chemopreventing cancer while the parent application is directed to a reduced scope of the compounds for chemopreventing cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



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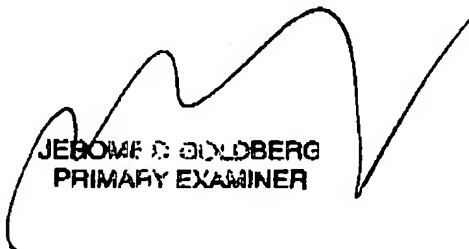
Application/Control Number: 10/084,391  
Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M. - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/T.G.D.  
February 3, 2003



JEROME C. GOLDBERG  
PRIMARY EXAMINER